IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC., a Delaware corporation,	)	
Plaintiff,	)	
v.	)	C. A. No. 05-590 (GMS)
DEXCOM, INC., a Delaware corporation,	)	
Defendant.	)	

ABBOTT DIABETES CARE'S
OPPOSITION TO DEXCOM'S MOTION TO DISMISS

MORRIS, NICHOLS, ARSHT & TUNNELL

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INTRODUCTION

DexCom's motion to dismiss ignores the controlling legal standards under Rules 12(b)(6) and 12(b)(1). Applying the correct legal standards demonstrates that DexCom's motion has no merit.

A. DexCom's Rule 12(b)(6) Motion Ignores The Relevant Standard.

Although seeking dismissal of Count II under Rule 12(b)(6), DexCom, Inc. ("DexCom") relies exclusively on summary judgment cases decided under Rule 56, as well as factual arguments derived from nine exhibits and an employee's affidavit. Dismissal motions under Rule 12(b)(6), however, are resolved based on the four corners of the complaint, and the complaint's allegations are accepted as true and accurate.

DexCom nevertheless asks this Court to disregard Abbott Diabetes Care's ("Abbott") allegations. For instance, Abbott specifically alleges that DexCom's infringing activity at trade shows was "not exempted by 35 U.S.C. § 271(e)" because the "products displayed at the trade shows were manufactured for the purpose of showcasing at the trade shows rather than for the purpose of gathering information for submission to the FDA." Complaint at ¶¶ 17, 28. DexCom, however, seeks dismissal based on the exact opposite factual allegation, characterizing trade shows filled with product booths as "scientific conferences" and asserting that it displayed samples only "for the purpose of obtaining FDA approval." (Declaration of Andrew K. Balo at ¶ 3). DexCom asserts that it was merely trying to find physicians to run "possible" clinical trials to obtain FDA approval – a claim belied by the fact that it had previously trumpeted to the marketplace that the FDA had indicted no more clinical trials were necessary.

Obviously, such factual disputes are not susceptible to resolution through a pre-discovery motion to dismiss under Rule 12(b)(6). Nor are they the proper subject of resolution through "judicial notice," as DexCom inexplicably implies. A patent infringer simply cannot obtain dismissal by arguing through an employee affidavit that it is entitled to protection under § 271(1)(e). *Ventrassist Pty. Ltd. v. Heartware, Inc.*, 377 F. Supp. 2d 1278, 1288 (S.D. Fla. 2005). As discovery will confirm, DexCom's infringing activities were not protected by § 271(e)(1). DexCom hyped its product at trade shows with stylized product samples, which were part of a glitzy advertising display that had nothing to do with obtaining FDA approval. Instead, DexCom was trying to generate buzz and excitement about its product in anticipation of its impending commercial launch. Such activities are not protected by § 271(e) and are certainly not the proper subject for dismissal under Rule 12(b)(6) based on the pleadings alone.

B. DexCom's Rule 12(b)(1) Motion Ignores The Relevant Standard.

DexCom also seeks dismissal of Count I under Rule 12(b)(1), but it ignores the legal standard created by the Federal Circuit, which has repeatedly held that declaratory jurisdiction exists when (1) the accused infringer has engaged in "meaningful preparation" to engage in future infringing activity and (2) has declined to reverse course after the patentee indicates that it is prepared to file suit. Because DexCom has filed for expedited FDA approval, devoted millions and years to preparing for infringing activity, and then continued to promote its product at trade shows after Abbott stated it was prepared to file suit, there is no serious debate that Abbott satisfied both prongs of the Federal Circuit's standard.

In fact, DexCom does not even discuss that standard and, instead, proposes a new standard that would make declaratory judgment actions impossible before FDA approval. According to DexCom, Count I is "premature" simply because the FDA has not yet approved its product and/or could theoretically ask DexCom to change its product. If such speculative possibilities could eliminate jurisdiction, no patent owner could ever file an infringement action until after the infringing product hit the market.

That is not the law. Courts look at the "practical likelihood" of infringing activity in the near future. Here, DexCom's approval is not only a practical likelihood, it is a foregone conclusion. In a separate motion, Abbott is seeking jurisdictional discovery to confirm that fact. But even publicly-available information demonstrates that DexCom's approval is imminent – it has successfully completed all clinical trials, passed its commercial inspections, and comprehensively answered all of the FDA's stated concerns. And DexCom itself has stated that it expects approval in the second quarter of 2006. In fact, there are no more steps in the application process. The FDA could approve DexCom's application at any time.

There is no question that declaratory jurisdiction exists in these circumstances. Abbott simply is not required to wait until ***after*** it has been injured by DexCom's product launch to protect its patent rights. That is the whole point of declaratory jurisdiction – to give companies like Abbott the ability to seek relief ***before*** the damage is done. Thus, the Court should deny DexCom's motion.

ARGUMENT

I. DEXCOM'S RULE 12(B)(6) MOTION SHOULD BE DENIED

A. DexCom Cannot Show "Beyond Doubt" That Abbott Can Prove "No Set Of Facts" Consistent With Its Allegations That Establish Patent Infringement.

Dismissal under Rule 12(b)(6) is appropriate only when "'it is clear that no relief can be granted under any set of facts that could be proved consistent with the allegations.'" *H.J. Inc. v. Northwestern Bell Tel. Co.*, 492 U.S. 229, 249-50 (1989) (quoting *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)). In fact, it must be "beyond doubt" that the "pleader can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). And when making that assessment, district courts must "construe[] the facts in favor" of the plaintiff. *Stiner v. Univ. of Delaware*, 243 F. Supp. 2d 106, 116 (D. Del. 2003).

DexCom makes no serious effort to meet the standard for dismissal under Rule 12(b)(6). In fact, it implicitly acknowledges that it cannot meet the standard by attempting to contradict Abbott's allegations with extraneous exhibits and an employee affidavit – an affidavit it asserts should "assure the Court that DexCom has acted within 35 U.S.C. § 271(e)(1)" or, in other words, should "assure the Court" that Abbott's allegations are incorrect. (DexCom Br. at 17 n.8).

Obviously, this is not an appropriate argument for a motion to dismiss, particularly when Abbott plainly states a claim and specifically alleges that DexCom's activities were not protected by § 271(e)(1). Section 271(e)(1) applies, on its face, only when the infringing activity is "*solely* for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or

sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1) (emphasis added). And just three months ago – in a decision that DexCom fails to cite – the Supreme Court held that § 271(e)(1) presents a factual issue about whether there is a "reasonable basis for believing that [disputed] experiments will produce the types of information that are relevant to an IND or NDA" filing with the FDA. *Merck KGaA v. Integra Lifesciences I, Ltd.*, ___ U.S. ___.

Abbott's complaint alleges specific facts taking DexCom outside the protection of § 271(e)(1) under the *Merck* standard. Abbott alleges that DexCom made infringing products "for the purpose of showcasing [them] at the trade shows rather than for the purpose of gathering information for submission to the FDA" and, similarly, that "DexCom's manufacture of its product for the purpose of showcasing it at trade shows constitutes an infringing act, not exempted by 35 U.S.C. §271(e)(1) relating to the collection of information for submission to the FDA." (Complaint at ¶¶ 16 , 17, and 28).

That ends the analysis because Abbott's allegations must be accepted as true under Rule 12(b)(6). DexCom nevertheless asks this Court to disregard Abbott's allegations. Specifically, DexCom alleges that the FDA "may require" additional clinical trials for DexCom's STS system and that it really made the commercially-slick samples to seek clinical investigators at trade shows to "prepar[e] for possible additional clinical trials." (DexCom's Op. Br. at 15-16). To support these allegations, DexCom relies on a declaration from one its own employees (D.I. 8) and more than 400 pages of exhibits (D.I. 7).

Just two months ago, however, the Southern District of Florida rejected an identical effort by an accused infringer. In the context of a motion to dismiss under Rule

12(b)(6), the infringer – just like DexCom – made arguments and filed an employee's affidavit claiming that its activities were protected by § 271(e)(1). *Ventrassist Pty Ltd. v. Heartware, Inc.*, 377 F. Supp. 2d 1278, 1288 (S.D. Fla. 2005), 2005 U.S. Dist. LEXIS 18457 (S.D. Fla., 2005). The district court found, not surprisingly, that an accused infringer cannot obtain dismissal by contradicting a complaint's allegations. *Id.* In fact, the district court found that § 271(e)(1) is never the proper subject of a motion to dismiss under Rule 12(b)(6) because § 271(e)(1) is an affirmative defense and "Plaintiffs are not required to negate an affirmative defense in their complaint." *Id.* at 1281.

For the very same reasons, this Court should reject DexCom's motion to dismiss. Abbott has unquestionably stated a claim for patent infringement, and specifically alleged that DexCom's activities were not for the purpose of gathering information for the FDA. Thus, DexCom's motion should be denied.

B. DexCom's Summary Judgment Cases Under Rule 56 Provide No Basis For A Motion To Dismiss Under Rule 12(b)(6).

In an effort to obtain dismissal despite Abbott's clear allegations, DexCom relies solely on pre-*Merck* summary judgment cases. In each case that DexCom cites, however, the issue was resolved on summary judgment under Rule 56, not on the pleadings under Rule 12(b)(6). *Telectronics*, 982 F.2d at 1521 (reviewing an "order granting the defendant's motion for summary judgment"); *AbTox Inc. v. Exitron Corp.*, 122 F.3d 1019, 1020 (Fed. Cir. 1997) (reviewing "cross motions for summary judgment"); *Nexell Therapeutics, Inc. v. Amcell Corp.*, 199 F. Supp. 2d 197, 198-199 (D. Del. 2002) ("AmCell moved for summary judgment of non-infringement" based on 35

U.S.C. § 271(e)(1)); *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1270 (N.D. Cal. 1991) (considering cross motions for summary judgment).

DexCom also completely ignores *Merck*, where the Supreme Court held that § 271(e)(1) turns on whether there is a "reasonable basis" for concluding that the disputed activity would "produce the types of information" filed with the FDA. *Id.* Far from suggesting this was a legal issue susceptible to resolution on the pleadings under Rule 12(b)(6), the Supreme Court declined to review "the sufficiency of the evidence" supporting a *jury's verdict* and, thus, remanded the case for further proceedings before the Federal Circuit. *Id.*

DexCom's own pre-*Merck* cases are consistent. In *Teletronics*, for instance, the Federal Circuit affirmed summary judgment only because the "basic facts [were] undisputed." *Telectronics Pacing Systems v. Ventritex, Inc.*, 982 F.2d 1520, 1521 (Fed. Cir. 1992). The court explained that the accused infringer presented evidence showing that its medical conference "demonstrations ha[d] all been set up for the purpose of obtaining clinical investigators," which the court found supported summary judgment "[a]bsent some showing that [the infringer's proffered] purpose is disputed." *Id.* at 1523. It further noted that the "fact that some non-physicians may have seen the device at the conferences is merely incidental and of minimal import, since only physicians can implant the device." *Id.*

Here, of course, Abbott *does* dispute the notion that DexCom, a small company with limited resources, spent considerable resources setting up glitzy product displays simply to solicit clinical investigators for unspecified, "possible" clinical trials – a claim that is all the more suspect because the FDA had previously indicated no more

trials would be necessary. (Exhibit A (DexCom July 25, 2005 Press Release). Moreover, unlike in *Teletronics*, DexCom's product *is* implanted by non-physician patients who attended both conferences in droves, making it all the more clear that DexCom was simply generating buzz in anticipation of a product launch. Given these facts, Abbott quite specifically alleged that DexCom made product samples simply "for the purpose of showcasing [them] at the trade shows rather than for the purpose of gathering information for submission to the FDA." (Complaint at ¶¶ 16 , 17, and 28).

It is simply not reasonable, given that allegation, to seek a pre-discovery dismissal under Rule 12(b)(6), which requires that Abbott's allegations be accepted as true and accurate. DexCom's own affidavit leaves open many factual questions that will be resolved through discovery. Did DexCom actually solicit any clinical investigators at the conferences? Did it bring materials to do so? Did it collect the names of potential investigators? Also, did DexCom make special versions of the infringing product for the trade shows? If so, why? Why was it necessary to make special versions to attract clinical investigators? And, in fact, why was it necessary at all to make and bring product samples to the trade shows? After all, DexCom alleges the samples were always kept under glass and were not used in actual demonstrations. Finally, what do DexCom's internal documents say? Do they support or undermine DexCom's current story that it was merely looking for clinical investigators for "possible" trials that the FDA had previously indicated would not be necessary?

In the end, there is no basis for granting DexCom's motion to dismiss. Abbott has specifically alleged facts demonstrating that DexCom's activities infringed

Abbott's patents and were not protected by § 271(e)(1). Nothing more is required at the notice pleadings stage.[1]

II. DEXCOM'S RULE 12(B)(1) MOTION SHOULD BE DENIED

DexCom also ignores the controlling legal standard when seeking dismissal of Count I under Rule 12(b)(1). DexCom argues that Abbott's action is "premature" because it has not yet obtained FDA approval and, thus, has not commercially launched its product. This argument has no merit.

A. Abbott Indisputably Meets The Federal Circuit's Two-Part Test For Declaratory Jurisdiction.

Contrary to DexCom's argument that FDA approval is required for jurisdiction, the Federal Circuit has long held that patentees may seek a declaration that a party will infringe in the future. *Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990). The accused infringer "need not have actually produced or be selling the product at issue as long as it has engaged in 'present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.'" *Biogen, Inc. v. Schering AG*, 954 F. Supp. 2d 391 (D. Mass. 1996) (quoting *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993)).

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[1] Abbott also objects to DexCom's request for the Court to take judicial notice of its various press releases and SEC filings and, in doing so, to also accept the truth of statements made in those documents. That is not a proper use of judicial notice. DexCom is seeking judicial notice of easily-disputed facts regarding its purpose for making the product samples in question as well as the prospect and likelihood of clinical trials. But Federal Rule of Evidence 201 only applies to facts "not subject to reasonable dispute." Fed. R. Evid. 201 (3d Cir. 200) (judicial notice of properly-authenticated public disclosure documents filed with SEC is appropriate for proving documents' content not truth of their content) (citing *Kramer v. Time Warner*, Inc., 937 F.2d 767, 774 (2d Cir. 1991)).

Based on that principle, the Federal Circuit has developed a two-part test for determining whether declaratory jurisdiction exists. Under that test, a justiciable controversy exists when: (1) the defendant is "engaged in an activity directed toward making, selling, or using subject to an infringement charge under 35 U.S.C. § 271(a), or [is] making meaningful preparation for such activity;" and (2) the defendant "indicate[s] a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming." *Lang*, 895 F.2d at 764.

DexCom never denies that Abbott has satisfied this two-part test. Nor could it. With respect to the "meaningful preparation" prong of the analysis, DexCom has spent years and millions of dollars preparing to commercially launch its infringing product, running extensive clinical trials, and filing a voluminous PMA application seeking FDA approval to market that product. (*See, e.g.*, Exhibit F at 2, 7, 10-12) (Transcript of CEO Speech, June 23, 2005)). In fact, almost the entire company is likely now devoted to getting that product on the market in violation of Abbott's patents. (*See id.* at 2). There can be no better evidence of "meaningful preparation." *See, e.g., Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1008-1009 (N.D. Ill. 2001) (stating that filing FDA application, "as both parties recognize, means that defendant is ready or has at least made meaningful preparations to be ready to market the allegedly infringing product").

With respect to the second element, DexCom continued to promote its product at trade shows after Abbott indicated it was prepared to file suit and, thus, DexCom has indicated a refusal to change course. Complaint at ¶ 19. Indeed, even though it has long known about Abbott's patents and has never denied its product would

infringe those patents, DexCom has continued to this day with its efforts to obtain expedited FDA approval. (*See* Exhibit E, September 12, 2005 Press Release). Thus, there is no dispute that Abbott has satisfied the Federal Circuit's two-part standard.

B. DexCom's Argument That FDA Approval Is Required For Jurisdiction Ignores The Law and The Facts.

1. FDA Approval Is Not Required For Declaratory Jurisdiction.

Rather than focusing on the Federal Circuit's standard, DexCom argues that this lawsuit is "premature" because things could possibly change given that the FDA still retains the authority to reject its product and/or require a change in the product. (DexCom's Op. Br. at 1). But accepting that argument would automatically preclude declaratory judgment actions before the FDA approves an infringing product.

That is not the law. Declaratory judgment actions are "proper even though there are future contingencies that will determine whether a controversy ever becomes real." WRIGHT & MILLER, 10 Fed. Pract. & Proc. Civ. 3d §2757. To determine whether to exercise jurisdiction in such circumstances, courts simply "focus on the practical likelihood that the contingencies will occur." *E.R. Squibb & Sons, Inc. v. Lloyd's & Cos.*, 241 F.3d 154, 177 (2d Cir. 2001) (quoting *Associated Indemnity Corp. v. Fairchild Indus., Inc.*, 961 F.2d 32 (2d Cir. 1992)); *Chevron U.S.A. Inc. v. Traillour Oil Co.*, 987 F.2d 1138, 1153 (5th Cir 1993) (same); *Seippel v. Jenkens & Gilchrist, P.C.*, 341 F. Supp. 2d 363, 383 (S.D.N.Y. 2004) (same); *Molitch v. Brotman*, No. Civ. A. 96-7742, 1997 WL 431008, at *2 (E.D. Pa. July 15, 1997) (noting that declaratory plaintiff need not establish that the prospect of injury "is a mathematical certainty" and, instead, jurisdiction is appropriate if the threat of future injury is "real and substantial."); WRIGHT

& MILLER, 10 Fed. Pract. & Proc. Civ. 3d §2757 (courts should look to the "practical likelihood that the contingencies will occur…in determining whether an actual controversy exists").

This is common sense. If speculative possibilities were enough to defeat declaratory jurisdiction, patent holders could never sue before the infringer actually launched its product and, thus, inflicted the damage the patentee was attempting to avoid. Yet, courts routinely entertain such declaratory judgment actions before the damage occurs and before FDA approval. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997) (affirming jurisdiction about 16 months before FDA approval and marketing); *Kos Pharm., Inc. v. Barr Labs, Inc.*, 242 F. Supp. 2d 311, 312, 318 (S.D.N.Y. 2003) (finding jurisdiction about a year or more before FDA approval based on a counterclaim to a March 2002 complaint where the earliest estimated approval date was March 2003); *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1007-1008 (N.D. Ill. 2001) (finding jurisdiction about 19 months before FDA approval where the complaint was filed in September 2000 and FDA approval was expected in June 2002).

Indeed, filing an application seeking FDA approval is exactly the sort of "concrete steps taken with the intent to conduct [infringing] activity" the courts find sufficient to provide declaratory judgment jurisdiction. *See, e.g., Glaxo*, 110 F.3d at 1571 (affirming jurisdiction based on filing of FDA application); *Takeda Chem. Indus., Ltd. v. Watson Pharm., Inc.*, 329 F. Supp. 2d 394, 402 (S.D.N.Y. 2004) (upholding jurisdiction based on application filing alone because "applying for FDA approval, show[s] that [party] has taken significant steps towards manufacturing and testing its…products"); *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 525 (S.D.N.Y. 2002)

("there is no question that all Defendants seek or have obtained FDA approval to sell the proposed ANDA product within the near future; therefore, the actual controversy requirement is met and the declaratory judgment action will be entertained"); *Glaxo, Inc. v. Torpharm, Inc.*, No. 95 C 4686, 1997 WL 282742, at *3 (N.D. Ill. May 18, 1997) ("[s]ince there is no question that TorPharm seeks imminent FDA approval to sell a [drug] in the near future, the actual controversy requirement is met and Glaxo's declaratory judgment action will be entertained").

In support of its argument that actual FDA approval is required to support jurisdiction, DexCom relies exclusively on cases decided before the Federal Circuit's decision in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir 1997), where the Court made it clear that FDA approval was *not* necessary for jurisdiction and, in fact, upheld jurisdiction even though FDA approval and actual marketing was over a year away. And, contrary to DexCom's position, no court has ever held that there is a special rule for medical device cases – in contrast to pharmaceutical cases – requiring FDA approval for jurisdiction. Instead, each of DexCom's cases simply holds that it was too early in the application process to entertain jurisdiction. For instance, in *Telectronics Pacing Systems v. Ventritex*, the Federal Circuit noted that the product "was *years away* from approval" and that the applicant "had only recently begun clinical trials." 982 F.2d 1520, 1527 (Fed. Cir. 1992) (emphasis added). Thus, *Teletronics* certainly does not, as DexCom claims, stand for the proposition that FDA approval is required for declaratory jurisdiction.

2. DexCom's Approval Is Not Only A Practical Likelihood, It Is A Foregone Conclusion.

Unlike in *Telectronics*, DexCom had not just begun clinical trials and is not "years away" from approval. On the contrary, DexCom has successfully completed each and every step of the application process, including clinical trials, commercial inspections, and the pivotal 100-day meeting with the FDA. (Declaration of Timothy Goodnow at ¶ 5 filed contemporaneously herewith). As explained in the accompany affidavit from Abbott's Vice President of Research & Development, Timothy Goodnow, the FDA could approve DexCom's application at any time. (*Id.*).

Through its requested discovery, Abbott fully expects to prove that FDA approval of DexCom's product is not only a practical likelihood, but a foregone conclusion. The public information, by itself, indicates that this is so. For instance, the FDA has granted "expedited" review of DexCom's product. (Exhibit B (DexCom Press Release May 12, 2005)). "Granting expedited review status means that a marketing application that is determined to be appropriate for expedited review is placed at the beginning of the appropriate review queue and receives additional review resources, as needed." (Exhibit C at Section C at 4 (Expedited Review Guidance from FDA)).

DexCom also already had a pivotal meeting with the FDA – called the 100-day meeting – where the FDA was supposed to "inform [DexCom] of any identified deficiencies and what information is required to correct those deficiencies…." (Exhibit D at 1 (100-Day Meeting Guidance from FDA)). According to DexCom, the FDA did *not* identify any substantial deficiencies at that meeting. Instead, the FDA asked certain questions that DexCom "consider[ed] …. *readily answerable.*" (Exhibit A (DexCom

July 25, 2005 Press Release) (emphasis added)). Over six weeks ago, DexCom also announced that it "expect[ed] to provide the requested information in an expeditious manner." (*Id*). And DexCom recently provided that information to the FDA on September 12, 2005 in a filing it stated "comprehensively addresses" the FDA's questions. (Exhibit E, September 12, 2005 Press Release).

DexCom also completed its clinical trials. Contrary to its current claims that more trials may be necessary, DexCom previously announced that the FDA "did *not* make any request for DexCom to conduct additional clinical studies" at the 100-day meeting, which the FDA certainly would have done if it believed more clinical trials were actually necessary. (Exhibit A (emphasis added)). And DexCom has repeatedly stated that such clinical trials would *not* be necessary because it ***already*** "met [its] primary safety and efficacy end points" through its earlier clinical trials. (Exhibit F at 9) (Transcript of CEO Speech, June 23, 2005)).

DexCom also successfully passed its commercial inspections, which are also referred to as "audits." On August 2, 2005, DexCom "announced the successful completion of two key inspections related to the FDA review of the PMA application" (Exhibit G (DexCom August 2, 2005 Press Release). DexCom stated that "[s]uccessfully completing BIMO and QSR inspections is a very significant achievement for DexCom as we progress toward being a commercial enterprise capable of launching a product, *especially as the inspections occurred earlier than we would have expected, only four months after filing our first-ever PMA.* Since we filed our PMA application, we have continued to have a very interactive, timely and productive review process with the FDA." *Id.* (emphasis added)

FDA approval is all the more certain because, unlike Abbott, DexCom reportedly is seeking a lower-threshold approval called "adjunct" labeling. (Declaration of Timothy Goodnow at ¶¶ 6-9). Adjunct labeling means that DexCom's device would be used in conjunction with the traditional finger-stick testing and, thus, would be acting only as a "back-up" or "supplemental" method to a long-proven technology for measuring glucose levels. (Declaration of Timothy Goodnow at ¶ 8). In contrast, as the term suggests, replacement labeling means the device would replace finger-sticking. (*Id.*). Thus, Abbott's device would be the *only* method of measuring glucose for the patients. There will be no back-up system, making it all the more important that the device is fail safe. (*Id.*). Not surprisingly, adjunct labeling is much more readily available than replacement labeling. (Declaration of Timothy Goodnow at ¶¶ 6-9).

At this point, DexCom has cleared every regulatory hurdle. There are no more hurdles to clear. Thus, the FDA can approve DexCom's application at any time. (Declaration of Timothy Goodnow at ¶¶ 5, 10-17). In its most recent press release, which was prepared after Abbott filed this lawsuit, DexCom took pains to note that its regulatory successes do not "guarantee" approval of its product. (Exhibit E). In the most technical sense, that is true. The FDA generally does not "guarantee" that it will approve a product with 100% certainty. But absolute certainty is not required for declaratory jurisdiction. All that is required is a "practical likelihood," which certainly exists here where the public information indicates that DexCom's approval is imminent.

DexCom's arguments to the contrary also highlight why discovery is so important. To attempt to avoid this lawsuit, DexCom is claiming that it cannot reliably predict whether its product will be approved. But that simply is not true. The FDA

routinely advises applicants about whether it has concerns that would place approval in jeopardy and, indeed, often indicates exactly what information is necessary to obtain approval. In fact, the applicable regulations *required* the FDA to "inform [DexCom] of any identified deficiencies and what information is required to correct those deficiencies" at the 100-day meeting. (Exhibit D at 1). Thus, based on communications it has declined to share with Abbott, DexCom knows exactly what issues remain outstanding before the FDA and also knows definitively whether those issues present any meaningful obstacle to approval.

DexCom also has resisted discovery on its argument that the FDA might order it to change its product in a way that impacts the infringement analysis. There are multiple problems with this argument. First, any meaningful change in the product would require new clinical trials to determine if the changes impact the device's safety and operations. Yet, at the 100-day meeting, the FDA did not ask for any clinical trial and, thus, almost certainly will not be asking for any changes to the product. This is confirmed by the FDA's decision to conduct manufacturing inspections, which it would not do if it planned to request a change in the product that would, inevitably, impact the manufacturing process. (Declaration of Timothy Goodnow at ¶¶ 12, 13). Indeed, DexCom has implicitly confirmed that its product is in its final form by hyping and showcasing the product at trade shows.

And even if DexCom's product were not in its absolute final form, which it clearly is, declaratory jurisdiction still exists. In *RDP Tech., Inc. v. N-Viro Int'l Corp.*, No. Civ A 00-697-RRM, 2001 WL 1083762 (D. Del. Sept. 17, 2001), for instance, the court found jurisdiction existed for a waste treatment process even thought the facility

was still under construction and, thus, the allegedly infringing process was not in its final form. *Id.* at *4-*5. The court explained that "given the amount of time, money and planning involved in the development of the…facilities, the plaintiff has a right to show that the facilities will infringe upon opening." *Id.*

Similarly, DexCom has devoted years and millions to its efforts to market an infringing product. And even if, after all this time, the FDA now reversed course and required a change to that product, DexCom makes no effort to explain what specific changes are even a remote possibility and how any such changes would impact the infringement analysis. No such explanation is possible. Abbott has four broad pioneering patents on the technology that DexCom is using without permission. Absent a complete overhaul of its product, DexCom simply cannot avoid these patents. A little tweak here or there will make no difference. This a-product-change-is-possible argument also should not be accepted without allowing discovery on the issue. Based on its discussions with the FDA, DexCom certainly knows whether a product change is under consideration. DexCom should not be permitted to claim in this lawsuit that product changes are possible while withholding the evidence that will show whether that claim is accurate and, if so, whether any such possible changes would be at all relevant to the infringement analysis.

In the end, this is simply not a case like *Teletronics* where an applicant is just beginning clinical trials and is "years away" from approval. Instead, as in *Novopharm*, DexCom is "systematically attempting to meet the applicable regulatory requirements" and, in fact, has cleared all the regulatory hurdles and has projected that it will be approved in the spring of 2006. Accordingly, declaratory jurisdiction exists.

CONCLUSION

For the foregoing reasons, the Court should deny DexCom's motion to dismiss.

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CERTIFICATE OF SERVICE

I hereby certify that on September 22, 2005, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

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Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on September 22, 2005 upon the following individuals in the manner indicated:

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